Eur J Vasc Endovasc Surg **30**, 52–56 (2005)
doi:10.1016/j.ejvs.2005.02.052, available online at http://www.sciencedirect.com on SCIENCE DIRECT®

A Randomized Prospective Study of Valvulotome Efficacy in *In situ* Reconstructions

J. Malmstedt,* R. Takolander and E. Wahlberg

Department of Vascular Surgery, Karolinska University Hospital, Stockholm, Sweden

Objectives. *To compare the efficacy of valvulotomes during* in situ *bypass surgery.*
Design. *A randomized prospective blinded study.*
Materials and methods. *Thirty PAD patients scheduled for infrainguinal greater saphenous vein bypass were randomized to use of adjustable or fixed valvulotomes for valve destruction. Valvulotomy was performed after construction of the proximal anastomosis. The efficacy of valve destruction was determined by angioscopy after completion of the distal anastomosis by a separate blinded examiner.*
Results. *A total of 123 valves were evaluated, 61 after use of an adjustable and 62 with a fixed valvulotome. There was no difference* (p=*.88) in number of retained valves between the two groups* (n=*16, 17, respectively). The majority of incompletely destroyed valves were found in the proximal parts of the graft (46%, 13 out of 28). The primary patency at 30 days was 100 and 79%, respectively,* p=*.09).*
Conclusions. *No significant difference in efficacy between valvulotomes was found. Both types tend to miss a large proportion of proximal valves.*

Keywords: Valvulotomy; In situ bypass grafts; Vascular reconstruction; Infrainguinal bypass.

Infrainguinal reconstruction using the *in situ* technique for preparation of the saphenous vein was first described by Hall 1964[1] and further developed by Leather.[2] With this technique, total valve disruption is probably essential for achieving good results. Despite this goal, residual valve cusps are reported to occur with frequencies between 12 and 45% after *in situ* bypass surgery.[3–7] Up to 15% of early graft failures are caused by residual valves,[8–10] therefore, it is important that there are improvements in valve destruction techniques. Especially, when considering the fact that the limb salvage and patency rates after reoperation due to early graft failure are poor,[11,12] and secondary procedures to assist patency are associated with considerable morbidity.[13,14]

One development to facilitate valve destruction and improve patency is the adjustable valvulotome (AV).[7,15] With fixed size valvulotomes it is difficult to accomplish adequate valve destruction in the proximal parts of the vein[3] and there is a substantial risk of endothelial damage.[4,16–18] The AV is designed to accomplish good valve destruction in the relatively wide proximal part of the vein without causing damage to the endothelium in the distal part. Theoretically this improvement should be favourable and may decrease the rate of residual valve cusps, but has to our knowledge never been evaluated thoroughly. The purpose of this study was, therefore, to evaluate and compare the effectiveness of AV and fixed valvulotome (FV) valve destruction.

Materials and Methods

Patients

Thirty patients scheduled for infrainguinal *in situ* bypass surgery with the great saphenous vein (GSV) at the Karolinska Hospital were randomized to use of either AV or FV. Patients were included between October 2000 and April 2004. Patients were included if they consented to participate and an experienced angioscopist was available. Patient characteristics, indication for surgery and type of procedure are shown in Tables 1 and 2. Patients underwent preoperative angiography, duplex vein mapping and a clinical examination, including ankle brachial index

* Corresponding author. Jonas Malmstedt, MD, Department of Vascular Surgery, Karolinska University Hospital, 171 76 Stockholm, Sweden.
E-mail address: jonas.malmstedt@karolinska.se

1078–5884/000052+05 $35.00/0

Table 1. Patient characteristics

Characteristic	Valvulotome		
	AV ($n=15$)	FV ($n=15$)	p^*
Men/women (n)	5/10	7/8	.71
Age median (range)	75 (52–86) years	77 (55–85) years	.97
Preop ABI median (range)	0.24 (0.00–0.62)	0.40 (0.13–0.69)	.12
Diabetes (n)	3	7	.26
Smoking (n)	9	7	.71
Hyperlipidemia (n)	9	9	1.00
Heart disease (n)	8	7	1.00
Hypertension (n)	11	9	.70
Renal failure (n)	1	1	1.00
Stroke (n)	2	5	.39
Previous vascular surgery (n)	5	6	1.00
COPD (n)	3	3	1.00

ABI, arterial ankle-brachial index; COPD, chronic obstructive pulmonary disease.
* Fischer's test, except for age and preoperative ABI where Mann–Whitney *U* test are used.

(ABI) measurements. They were followed up according to hospital routines. This included clinical examination at one month and duplex scanning at 1, 3 and 6 months postoperatively.

Surgery

The procedures were performed under epidural anaesthesia. In brief, arteries were accessed using a groin and an appropriate distal incision to expose the outflow vessel. Proximally, the GSV was divided at the confluence and the most proximal pair of valves was excised under direct vision by scissors. Patients were heparinized with 2500–5000 IU Heparin intravenously. The proximal anastomosis was constructed in an end-to-side manner to the common femoral artery using a running suture. The vein was then exposed to arterial pressure and the distal part of the vein was exposed. At that time patients were allocated either to use of a AV (Expandable LeMaitre valvulotome®, LeMaitre Vascular, USA) or a FV (Insitucat®, B. Braun Melsungen, Germany). The diameter of the largest head (2.5 or 3.0 or 3.5 mm) of FV used, the number of times the valvulotome was passed through the vein and the surgeon's estimation of graft flow (poor, fair, very good) after valvulotomy were registered. The distal anastomosis was constructed similar to the proximal anastomosis. GSV branches were identified preoperatively by handheld Doppler in addition to preoperative marking by Duplex and ligated. Finally angioscopy was performed through a spared side branch in the most proximal part of the vein. This was done by a separate blinded examiner not participating in the operation using a flexible 2.4 mm angioscope (Intramed® Reusable Angioscope, Baxter Healthcare Corporation, USA). The graft was inspected during flushing with warm Ringer solution administrated by a mechanical infusion pump controlled by a foot pedal (Intramed Endoscopic Irrigation Pump®, Baxter Healthcare Corporation, USA) at 80–250 ml/s. Arterial inflow was occluded during angioscopy. The angioscope was passed all the way to distal anastomosis and the inspection of the graft was performed while retracting the scope. Identified retained valves were cut by a Mill valvulotome, and missed side-branches that were found during angioscopy were marked and ligated.

Table 2. Indication for surgery, type of procedure and preoperative vein mapping data

	Valvulotome		
	AV ($n=15$)	FV ($n=15$)	p
Rutherford category[19]			
Severe claudication	2	3	.19*
Ischemic rest pain	6	1	
Minor ulcer	6	10	
Major ulcer	1	1	
Type of surgery			
Femoro-popliteal AK	4	3	.75*
Femoro-popliteal BK	6	5	
Femoro-crural	5	7	
Vein diameter [mm]			
Proximal median (range)	4.3 (3.5–8.0)	4.7 (2.5–6.1)	.37†
Distal median (range)	2.3 (1.9–5.3)	2.7 (2.0–4.3)	.50†
Smallest segment median (range)	2.2 (1.7–4.6)	2.5 (2.0–3.5)	.64†

AK, above knee; BK, below knee.
* Chi-square test.
† Mann–Whitney *U* test.

Study design

The study was approved by the local ethics committee. Patency and indications for surgery were defined according to Rutherford.[19] Closed envelopes were used for randomization. Three vascular surgeons who were internally validated performed all angioscopies and assessed valvulotomy efficacy. The number and location of valves cut and the effectiveness of valvular destruction were recorded. A scale with three grades was used: missed, partially cut or completely cut as shown in Fig. 1. The definitions were as follows: a missed valve was defined as both cusps cut no more than half. A completely cut valve was defined as both cusps cut more than half the way to the vein wall. A partially cut valve was defined as conditions between missed and completely cut. For the analysis the partial and missed groups were combined and named 'incomplete'. The primary endpoint for the study was the number of insufficiently cut valves (missed or partially cut). A secondary endpoint was patency at follow-up.

Statistics

Differences in categorial variables between groups were analyzed by Chi-square and Fisher's exact test. Continuous variables were evaluated by Mann–Whitney test. Results with $P<0.05$ was considered significant. One person (JM) performed all the analyses after completion of the study.

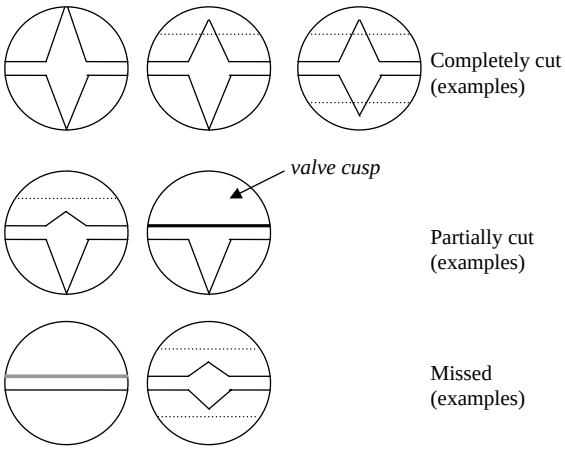

Fig. 1. Definitions of valve destruction efficacy used during angioscopy assessment. (The hatched lines represent half the cusp diameter).

Results

Fifteen patients were randomized to each group but one from each was excluded from the analysis of the primary endpoint due to failure of the angioscopy instrument. There were no statistical significant differences in risk factors, indication, or type of surgery between groups (Tables 1 and 2). Estimated graft flow was considered as fair or very good in all patients after valvulotomy, but to achieve that the valvulotomes needed to be passed through the vein slightly more times in the FV group (median 3.2, range 2–6 vs. median 2.5, range 2–3 times, $p=.09$). Two valvulotome related complications occurred, both in the FV group. One was a perforation of the vein wall adjacent to a branch and the other an intramural haematoma (and early occlusion) due to vein damage, which probably was caused by the valvulotome.

Sixty-one valves were assessed in the AV group and 62 in the FV group. The proportion of incompletely cut valves was similar ($p=.88$) between the valvulotomes (AV 26%, $n=16$ vs. FV 27%, $n=17$) (Table 3). The majority of missed cusps were located proximally (Fig. 2). It was slightly more common to have an incompletely cut proximal valve in the AV group (57% 8/14 vs. 36% 5/14) but the difference was not statistically different ($p=.22$). The location of incompletely cut valves is depicted in Fig. 2.

Primary patency at 30 days was 89% (Table 4), (100% 12/12 in AV group and 79% 11/14 in FV group, $p=.09$). There were three occlusions within 5 days in the FV group, one of these were probably related to vein damage by the valvulotome. This graft was successfully reopened. One patient in the AV group died with a patent graft 24 days after surgery due to

Table 3. Results, valve disruption and graft flow assessment by the surgeon

	Total	Valvulotome		
		AV ($n=14$)*	FV ($n=14$)*	p
Inspected valves	123	61	62	
Complete	90	45	45	.88†
Incomplete	33	16	17	
Missed valves	4	3	1	.26†
Partially cut	29	13	16	
Number of graft passings	Mean (range)	2.5 (2–3)	3.2 (2–6)	.09‡
Flow		($n=15$)*	($n=15$)*	
Fair	6	2	4	.36†
Very good	22	13	11	
Poor	0	0	0	

* Number of patients. One patient omitted from each group due to angioscopic failure.
† Chi-square test.
‡ Mann–Whitney *U* test.

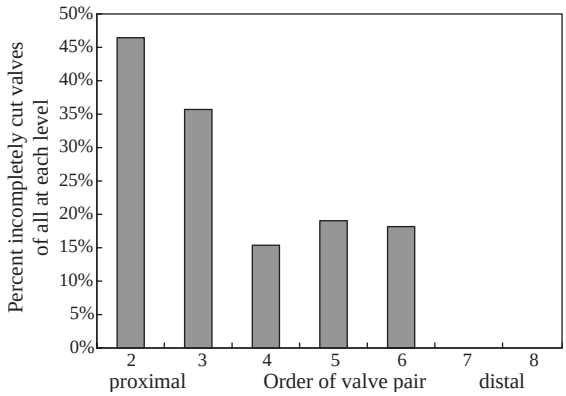

Fig. 2. Location of incompletely cut valves. (The first (proximal) valve was cut with a pair of scissors under direct vision).

congestive heart failure and another patient, also in the AV group died after 30 days due to pulmonary oedema and multiple organ failure. There was one minor amputation in the AV group and two major amputations (one in the FV and one in the AV group) within 30 days. Midgraft stenoses, a marker of suspicious valve remnants, were detected with duplex scanning in one graft in the AV group and two grafts in the FV group. The stenoses were detected after 76, 72 and 213 days, respectively. One of these grafts in each group occluded after 221 and 388 days, respectively. At a mean follow-up of 224 days the primary patency was 69% (80% the AV and 58% in the FV group, $p = .40$).

Discussion

The principal finding in this study is the similarity of AV and FV valve destruction efficiency. The outcome data is extremely unreliable due to few cases and incomplete follow-up. The number of valve remnants in the grafts during follow-up was similar. While this study may have missed minor differences in efficacy due to lack of power, we believe that the results are by large valid. There are several possible explanations for the findings. The fact that most missed valves are found in the proximal part of the graft indicates that the vein diameter may be important. The diameter may particularly influence the results of AV use because retained valves tended to be more common with this valvulotome proximally. The maximum diameter of the AV hoop is 8 mm and the blade 6 mm. This may be too small for effective valve disruption in a wide vein. Our preoperative vein mapping data showed proximal vein diameters around 6–8 mm, which may become wider when the vein is put under arterial pressure. An important difference between the FV and AV is the size of the cutting blade. In the latter it is only about 1 mm whereas it equals the outer diameter (2.5–3.5 mm) in the former. This implies that the AV may cut only a small part of the valve cusp in a wide vein. On the other hand, the FV is designed to cut the cusp all the way to the vein wall aided by manual steering;[20] whereas the lack of centering mechanism will increase the risk of only cutting one of the two cusps in a wide vein. Another possible explanation to our results is that some of our veins may have valvular insufficiency. With the centered AV blades there is a substantial risk that less than half of the two cusps are cut.

The proportion of residual valve cusps (27%) in our patients is comparable to previous data from studies using either AV or FV assessed by angioscopy.[3,5,6,16,21] Ahlbäck *et al*. also noted that most missed valves (29%) were found in the proximal part of the vein when using an FV.[3] Thorne *et al*. used the same AV as in this study and reported residual valve cusps detected in half (17/32) of the patients, with a mean of two residual cusps per graft.[21] Substantially fewer grafts with retained valves were found by Dardik.[7] He also evaluated the same AV and found missed valves in only 2 of 25 grafts, as compared to our data where 12 of 14 grafts had retained valves. In that study, however, the number of valves inspected or the number of incomplete cut valves were not reported. The discrepancy in results may be due to differences in definitions of residual valves. Furthermore, this study was performed in 11 different centers, adding a substantial risk of interobserver variability. None of

Table 4. Primary patency life table

Interval (months)	No. at risk at beginning of interval	No. failed during interval	Withdrawn during interval	Interval failure rate*	Cumulative patency rate* (%)	Standard error* (%)
0–1	30	3	4	0.107	89	2.96
1–3	23	1	3	0.047	85	3.69
3–6	19	1	2	0.056	80	4.21
6–9	16	2	4	0.143	69	4.29
9–12	10	0	2	0.000	69	6.87

* Calculated according to Rutherford.[19]

these two studies were designed to evaluate valvulotome efficacy.

Accordingly our findings correspond to, and support most previous non-randomized studies. Together they suggest that complete valve disruption without endothelial damage is difficult to achieve and probably needs improvement. A proposed alternative to blind valvulotomy is to use the angioscopy-assisted technique.[10,22] The question whether insufficient valve destruction actually will affect patency could not be answered by this study, but a previous report indicate that it does.[21] Our attempt to compare patency rates is flawed by the small patient cohort and the correction of identified missed valves after angioscopy. The low frequency of valve remnants during follow-up also make it difficult to draw conclusions about valve remnants influence on graft function. The two major valvulotomy complications occurred in the FV group, but those may have happened by coincidence. That AV may cause less graft damage is plausible but not well supported in the literature.

In conclusion, insufficiently destroyed valves are very common but there is no large difference in efficacy between FV and AV. The latter valvulotome appears to overlook at least as many proximal valves as FV. There is a great need for further improvements in valvulotomy design and usage.

Acknowledgements

This study was supported by grants from the Swedish Heart and Lung Foundation and Karolinska Institute. We also thank our OR nurses Yvonne Norrbom and Karin Glenn for their assistance with this study.

References

1 Hall KV. The great saphenous vein used *in situ* as an arterial shunt after extirpation of the vein valves. A preliminary report. *Surgery* 1962;**51**:492–495.
2 Leather RP, Powers SR, Karmody AM. A reappraisal of the *in situ* saphenous vein arterial bypass: its use in limb salvage. *Surgery* 1979;**86**(3):453–461.
3 Alback A, Kantonen I, Ihlberg L, Lepantalo M. Valvulotomy of non-reversed saphenous vein bypass grafts: a randomised, blinded, angioscopy-controlled study. *Eur J Vasc Endovasc Surg* 1999;**18**(2):144–148.
4 Miller A, Stonebridge PA, Tsoukas AI, Kwolek CJ, Brophy CM, Gibbons GW *et al*. Angioscopically directed valvulotomy: a new valvulotome and technique. *J Vasc Surg* 1991;**13**(6):813–820 [discussion 821].
5 Wilson YG, Davies AH, Currie IC, Mcgrath C, Morgan M, Baird RN *et al*. Angioscopically-assisted *in situ* saphenous vein bypass for infrainguinal revascularisation. *Eur J Vasc Endovasc Surg* 1996;**12**(2):223–229.
6 Gilbertson JJ, Walsh DB, Zwolak RM, Waters MA, Musson A, Magnant JG *et al*. A blinded comparison of angiography, angioscopy, and duplex scanning in the intraoperative evaluation of *in situ* saphenous vein bypass grafts. *J Vasc Surg* 1992;**15**(1):121–127 [discussion 127–129].
7 Dardik H, Vazquez R, Silvestri F, Ibrahim IM, Sussman B, Kahn M *et al*. Experience with a new valvulotome for lower-extremity revascularization procedures by the *in situ* method. *Cardiovasc Surg* 1995;**3**(2):193–197.
8 Stept LL, Flinn WR, Mccarthy 3rd WJ, Bartlett ST, Bergan JJ, Yao JS. Technical defects as a cause of early graft failure after femorodistal bypass. *Arch Surg* 1987;**122**(5):599–604.
9 Donaldson MC, Mannick JA, Whittemore AD. Causes of primary graft failure after *in situ* saphenous vein bypass grafting. *J Vasc Surg* 1992;**15**(1):113–118 [discussion 118–120].
10 Miller A, Jepsen SJ, Stonebridge PA, Tsoukas A, Gibbons GW, Pomposelli Jr FB *et al*. New angioscopic findings in graft failure after infrainguinal bypass. *Arch Surg* 1990;**125**(6):749–754 [discussion 755].
11 Robinson KD, Sato DT, Gregory RT, Gayle RG, Demasi RJ, Parent 3rd PN *et al*. Long-term outcome after early infrainguinal graft failure. *J Vasc Surg* 1997;**26**(3):425–437 [discussion 437–438].
12 Baldwin ZK, Pearce BJ, Curi MA, Desai TR, Mckinsey JF, Bassiouny HS *et al*. Limb salvage after infrainguinal bypass graft failure. *J Vasc Surg* 2004;**39**(5):951–957.
13 Reoperations, redo surgery and other interventions constitute more than one-third of vascular surgery. A study from Swedvasc (The Swedish Vascular Registry). The Swedish Society for Vascular Surgery. *Eur J Vasc Endovasc Surg* 1997;**14**(4):244–251.
14 Ng RL, Davies AH, Magee TR, Tennant S, Horrocks M, Baird RN *et al*. Early reoperation rates after arterial surgery. *Eur J Vasc Surg* 1994;**8**(1):78–82.
15 Gangadharan SP, Reed AB, Chew DK, Conte MS, Belkin M, Whittemore AD *et al*. Initial experience with minimally invasive *in situ* bypass procedure with blind valvulotomy. *J Vasc Surg* 2002;**35**(6):1100–1106.
16 Parent 3rd FN, Gandhi RH, Wheeler JR, Gregory RT, Snyder SO, Gayle RG *et al*. Angioscopic evaluation of valvular disruption during *in situ* saphenous vein bypass. *Ann Vasc Surg* 1994;**8**(1):24–30.
17 Sayers RD, Watt PA, Muller S, Bell PR, Thurston H. Endothelial cell injury secondary to surgical preparation of reversed and *in situ* saphenous vein bypass grafts. *Eur J Vasc Surg* 1992;**6**(4):354–361.
18 Hager JC, Barman AA, Moideen AS, Chaudhry SS, Barman SA. Endothelial cell injury in the human saphenous vein: a comparative study of two valvulotomes. *Cardiovasc Surg* 1995;**3**(3):291–292.
19 Rutherford RB, Baker JD, Ernst C, Johnston KW, Porter JM, Ahn S *et al*. Recommended standards for reports dealing with lower extremity ischemia: revised version. *J Vasc Surg* 1997; **26**(3):517–538.
20 Enzler MA, Smith LL. Valve disruption for *in situ* vein bypass: use of a new technique. *Ann Vasc Surg* 1991;**5**(6):561–563.
21 Thorne J, Danielsson G, Danielsson P, Jonung T, Norgren L, Ribbe E *et al*. Intraoperative angioscopy may improve the outcome of *in situ* saphenous vein bypass grafting: a prospective study. *J Vasc Surg* 2002;**35**(4):759–765.
22 Stierli P, Aeberhard P. *In situ* femorodistal bypass: novel technique for angioscope-assisted intraluminal side-branch occlusion and valvulotomy. A preliminary report. *Br J Surg* 1991;**78**(11):1376–1378.

Accepted 15 February 2005
Available online 7 April 2005